

that the labeling directions are not adequate simply by failure of the labeling to include a statement that the drug is to be used for 'stomach ulcers.'<sup>1</sup> That such a requirement is a requisite of adequate directions for use is borne out by the decisions. The principle was well stated in *United States v. Various Quantities* \* \* \* '*Instant Alberty Food*,' 83 F. Supp. 882, 885 (D. C. D. C.) :

The words "adequate directions for use" necessarily relate to some purpose which is to be served by the use, and that purpose must be consistent with the intent of the Act as a whole to protect the public health. For what purpose are drugs used? Obviously, as a remedy for some ailment of the body. It seems equally obvious that no drug can be said to contain in its labeling adequate directions for its use, unless every ailment of the body for which it is, through any means, held out to the public as an efficacious remedy be listed in the labeling, together with instructions to the user concerning the quantity and frequency of dosage recommended for each particular ailment.

See also: *Alberty Food Products, a partnership, et al v. United States*, 194 F. 2d 463 (C. A. 9) ; *Colgrove v. United States* 176 F. 2d 614 (C. A. 9).

"Libelant also charges that the directions for use on the label of 'Tryptacin' are not adequate because, even if they were followed, a cure from stomach ulcers would not result. On this point, Libelant's witness, Dr. Barron, who possesses impressive qualifications, including the fact that he has diagnosed and treated numerous cases of stomach ulcers in the course of his practice, testified that the directions for use as they appear on the bottle label of 'Tryptacin' are not adequate. Dr. Barron gave as reasons for this statement the fact that every case of stomach ulcers must be treated as an individual problem; that other drugs as well as antacids are sometimes used in the treatment of stomach ulcers and that different antacids are used in different types of cases; that factors other than the administration of drugs are involved in the healing of an ulcer; that untreated or improperly treated stomach ulcers may become cancerous and unresponsive to surgery; and that stomach ulcers is a disease which should not be treated except under the supervision of a physician. Dr. Hugh A. McGuigan, who testified for claimant and who also possessed extensive qualifications in the fields of pharmacology and therapeutics, stated that in his opinion the directions for use on the label of 'Tryptacin' give to the user of the product sufficient directions to enable intelligent and safe self-treatment. Dr. McGuigan testified on cross-examination, however, that diet and rest, in addition to administration of an antacid, and other drugs, are sometimes factors in the treatment of stomach ulcers. In this last statement, Dr. McGuigan agreed in effect with Dr. Barron. It is apparent to me that the directions for use are not complete and consequently are inadequate.

"Findings of Fact, Conclusions of Law and an Order for Judgment will be entered accordingly."

In accordance with the above opinion, the court made its findings of fact and conclusions of law; and, on September 15, 1953, the court entered a decree of condemnation and destruction.

**4328. Adulteration and misbranding of laxative quinine tablets. U. S. v. 75 Packages \* \* \*. (F. D. C. No. 36214. Sample No. 56166-L.)**

**LIBEL FILED:** December 29, 1953, Northern District of New York.

**ALLEGED SHIPMENT:** On or about September 2, 1952, from Worcester, Mass.

<sup>1</sup> The Secretary of Health, Education, and Welfare, acting under Section 701 (a) of the Act, 21 U. S. C. 371 (a), has promulgated the following interpretative regulations of Section 502 (f) (1) of the Act; 21 U. S. C. 352 (f) (1) :

21 C. F. R. 1,106 *Drugs and Devices: Directions for use.*—(a) *Adequate Directions for use.* "Adequate directions for use" means directions under which the layman can use a drug . . . safely and for the purpose for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Statements of all conditions, purposes, or uses for which such drug . . . is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug . . . is commonly used; . . .

**PRODUCT:** 75 packages of *laxative quinine tablets* at Utica, N. Y., in possession of Bockman's Drug Store, Inc. Analysis showed that the article consisted of red compressed tablets containing quinine, cinchonine sulfate, aloin, gamboge, phenolphthalein, capsicum, and 0.59 grain of acetanilid.

**RESULTS OF INVESTIGATION:** The tablets were shipped in interstate commerce in bulk containers, and upon receipt by the consignee, they were repackaged and relabeled.

**LABEL, IN PART:** (Bulk container) "10,000 Tablets \* \* \* Pink Each tablet contains: Acetanilid ( $\frac{5}{8}$  gr.) 40 mg., Quinine Phosphate, Cinchonine Sulfate, Aloin, Gamboge, Phenolphthalein and Capsicum \* \* \* Caution: \* \* \* Frequent or continued use may cause a dependence upon laxatives"; (package) "Recommended For Colds, Coughs, La Grippe, Malarial Headaches and Neuralgia Bocan's Laxative-Quinine Compound Useful in the Treatment of \* \* \* Chills \* \* \* Fever Each Tablet contains  $\frac{1}{2}$  gr. Acetanilid \* \* \* Contents 20 Tablets."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the strength of the article in the packages differed from that which it purported to possess since the article contained more than  $\frac{1}{2}$  grain of acetanilid.

Misbranding, Section 502 (a), certain statements on the package label and in a leaflet enclosed with each package were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for colds, coughs, bronchial troubles, la grippe, catarrh, neuralgia, malarial troubles, malarial headaches, chills, and fever. The article was not an adequate and effective treatment for such purposes. Further misbranding, Section 502 (e) (2), the package label failed to bear the common or usual name of each active ingredient since aloin, gamboge, and phenolphthalein were not declared; and, Section 502 (f) (2), the labeling of the article in the packages failed to bear a warning that the article should not be taken in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, or a warning that frequent or continued use may result in a dependence on laxatives.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

**DISPOSITION:** February 6, 1954. Default decree of condemnation and destruction.

#### **DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\***

**4329. Adulteration of alpha-tocopherol and alpha-tocopheryl acetate.** U. S. v. Pharmaceutical Co. of New Jersey and Theodore R. Kupchik. Pleas of guilty. Fine of \$3 against company and \$1,500 against individual. (F. D. C. No. 33779. Sample Nos. 22855-L, 22859-L, 22860-L.)

**INFORMATION FILED:** April 13, 1953, District of New Jersey, against the Pharmaceutical Co. of New Jersey, a corporation, Bloomfield, N. J., and Theodore R. Kupchik, president of the corporation.

**ALLEGED SHIPMENT:** On or about June 7 and 18, 1951, from the State of New Jersey into the State of New York.

**LABEL, IN PART:** (Bottle) "Darrylle Chemical Co. 121 Broad St., New York 4, N. Y. 500 Grams Alpha Tocopheryl Acetate (Vitamin E Acetate)"; (ampul)

\*See also No. 4328.